

Remarks

Memorandum of Interview

Examiner Edwards kindly agreed to a personal interview with the undersigned, which was conducted on Monday, November 24, 2008. The interview was also attended by Supervisory Examiner Griffin. During the interview the art of record was discussed, in particular Batliwalla and Baer. Undersigned in particular noted the technical field of Batliwalla as well as the teachings of Baer. The undersigned explained that she would amend the claims as set forth herein so as to further highlight the differences between the current invention and the prior art. The undersigned showed the Examiners a model of a commercial embodiment of the claimed invention.

Examiner Edwards kindly agreed to call the undersigned after receiving this response to seek to address any outstanding issues to further the prosecution of this case.

General Remarks and Discussion of Rejection

Claims 1 to 47 are pending in this application. Claims 21 to 25, 28 and 29 are withdrawn. Claim 1 has been amended. Support for the amendment can be found in the preamble of claim 1 and on page 8 of the specification, in the paragraph starting on page 18. Claims 47 and 48 are new. Support for these claims can be found, e.g., on page 8, lines 1 to 16.

Double Patenting

On pages 2 and 3, the Office provisionally rejected claim 1 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 24 of co-pending appl. No. 10/972,294. The Office also provisionally rejected claim 5 over claim 31 and claim 6 over claim 32 of this application.

Applicants acknowledge these provisional rejections and will address the rejections, if appropriate, in a timely manner in accordance with MPEP §804 I.B(1).

Obviousness

Starting on page 3, the Office rejected claims 1 to 11, 19 to 20, 26, 31 to 34 under 35 USC§103(a) as being unpatentable over U.S. Patent 4,761,541 to Batliwalla et al. (hereinafter "Batliwalla") in view of U.S. Patent 5,128,257 to Baer (hereinafter "Baer") and further in view of 4,765,874 to Modes et al. (hereinafter "Modes").

The Office referred in particular to Batliwalla's claims 1 and 4. These claims disclose a device comprising a resistive element composed of a first material having a resistivity, wherein the first material may be a conductive polymer (claim 4) and may contain a conductive filler (claim 4). The first material is said to be bonded to a contact layer composed of a second conductive material (claim 1), with lower specific resistance at 23 °C than the first material.

The Office referred to Batliwalla's abstract as teaching an electrode.

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The Office drew the conclusion that Batliwalla teaches an electrode comprising every limitation of the instant claim, except using the electrode in a cuvette of at least one reaction chamber of a multiwell plate.

However, the Office submitted that Baer teaches using an electrode in a cuvette (see Fig. 3, see also col. 3, line 22 to 24), including two electrodes which are placed against the opposite walls of a flat-sided, open-topped cuvette (see col. 5, line 64).

Claim 1 requires:

"said at least one electrode is made of a conductive synthetic material which is, or is at least based on a plastic material which is doped with at least one conductive substance, and
wherein an overall concentration of said dope in said plastic material is 20 – 80 % w/w" (*emphasis added*)

Applicants submit that Batliwalla discloses electrical devices, in particular laminar heaters, containing materials including as Batliwalla's claim 1 and claim 4 recite, a resistive element composed of a first material (which may, per claim 4, be a conductive polymer), a contact layer composed of a second conductive material (which may, per claim 4, be a conductive polymer) and a further member in direct physical contact with the contact layer.

The abstract, the Office refers to for disclosure of an electrode, discloses (a) an electrical heater comprising a laminar resistive element, a plurality of electrodes, a metallic foil and a dielectric layer (lines 1-14) and, (b) an electrical device comprising first and second members having different resistivity and a thin contact layer of intermediate resistivity positions between the first and second member (lines 15 -18).

Applicants submit that the Office's citation does not provide any evidence that the electrode recited in the abstract is made of the conductive polymer recited in Batliwalla's claim 4. Applicants thus submit that the Office's showing with regard to Batliwalla is insufficient.

With regard to the disclosure by Modes, the Office argued that discovering optimum workable ranges of a general condition (here dope concentration) that is known, involves only routine skill. Applicants submit that it is well recognized that a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation (MPEP §2144.05 citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977)). Applicants could find no indication that the dope concentration recited in Modes is a result-effective variable for, e.g., Modes' corrosion resistance (see Office Action, page 4).

The Office is in this context also referred to new claim 46 and 47, that specify that the electrode is moldable/ injection molded. The dope range is chosen to ensure sufficient conductivity, while it is still possible for the electrode to be moldable/ injection molded.

However, as discussed during the interview, applicants have amended the claims to clarify that the claimed container:

"is for electroporation or electrofusion of cells, derivatives of cells, subcellular particles and/or vesicles and is, at least partially, formed by an outer limit which forms an inner chamber for receiving said solution"
(emphasis added)

The first of these limitations, while functional, provides structural differences as the recited function imposes structural limitations onto the claimed invention.

The second of these limitations stems from the preamble of the claim and, by being moved into the body of the claim, more clearly contributes to the definition of the claimed invention.

Applicants respectfully submit that it is well established that if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (MPEP §2143.01).

In *In re Ratti*, the court note that the suggested combination of references would *require a substantial reconstruction and redesign of the elements shown in* [the primary reference] as well as a change in the *basic principles* under which the [primary reference] construction was designed to operate. (*Emphasis added*). In *Ratti*, the modification suggested by the Office changed the basic principle of sealing from attaining sealing through a rigid, press-fit, interface between the components, to attaining sealing by providing a resilient interface between the components. *Id.* at 811-13. It was found that such a modification fundamentally changes the technical basis of how a seal performs its sealing function and how a sealed interface is attained.

Applicants respectfully submit that modifying Batliwalla 's electrode to work as an electrode for electroporation or electrofusion as claimed would both, require a substantial reconstruction and redesign of the elements shown in Batliwalla as well as change the basic principles under which Batliwalla was designed to operate. In particular, it is clear from the description of Batliwalla and its Figures that any electrode he discloses forms an integral part of a structure of, e.g., electrical devices such as sheet heaters, as described throughout his disclosure. Batliwalla also explains in col. 2 that his electrodes "appear to act both as current carriers and heat sinks in a way which minimizes the formation of hot-lines" (col. 2, lines 38-40). Applicants submit that thus modifying any electrodes of Batliwalla to operate as an electrode for electroporation or electrofusion would require a substantial reconstruction and redesign of the elements

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shown as well as fundamentally change the technical basis how Batliwalla's electrodes perform their function.

Irrespective of the above, applicants further submit that there is no motivation to modify Batliwalla with the teaching of Baer as the Office suggested.

It is well established that a prior art reference must be considered in its entirety, i.e., as a whole (See, MPEP §2141.02 citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)).

Baer, who indeed and in contrast to Batliwalla, describes a process and apparatus for electroporation of cell suspensions, discloses electrodes. The electrodes used by Baer are made from conductive material such as, e.g, aluminum:

Baer in particular states in the paragraph starting on line 66 of col. 4:

"The electrodes used in the apparatus of the present invention are made from conductive material such as platinum, gold, aluminum, stainless steel, titanium and alloys thereof, although other conductive materials may be used which, in general, are not toxic to the cells to be electroporated. The *above identified specific conductive materials are preferred* since such materials are not only non-toxic to most cells but in some cases certain cell-types can actually attach to and grow on the surface of such conductive materials" (emphasis added)

Accordingly, it appears that Baer was quite satisfied with the performance of the state of the art electrodes for electroporation in particular those made from conductive material such as platinum, gold, aluminum, stainless steel, titanium and alloys thereof.

Applicants submit that the Office has provided no reasoning for making the modification suggested apart from the Office's opinion that modifications of the prior art to meet the claimed invention would have been within the capabilities of the person of ordinary skill in the art (See MPEP §2143.01 reciting that a "statement that modifications of the prior art to meet the claimed invention

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would have been well within the ordinary skill of the art at the time the claimed invention was made . . . is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references"). In fact, applicants submit that Baer strongly indicates that there is no apparent reason to make the suggested modification.

In view of the above, applicants believe that the claimed invention is now in condition for allowance and sincerely urges the Office to call the undersigned at the number provided below to address any outstanding issue at the Office may identify.

The extension of time fees and fees for an additional two claims are submitted herewith. However, the Office is authorized to charge any additional fees required to undersigned's deposit account no. 50-3135.

Respectfully submitted,

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